Claim Rejection -35 USC 112, Claims 3 and 4
Examiner suggests that the specification "while being enabling for methods of producing disomic human embryonic cell lines" is not enabling for making "stem cell lines".
The specification incorporate several articles and patents that teach to "any person skilled in the art" of making stem cells. Patent specification need only describe and show possession of the invention in its totality and not teach (hybridtech v Monoclonal antibody inc 231U.S.P.Q.81 (federal circuit 1986)), herself, states that Thompson patents and reference's teach how to make stem cells from "normal" non trisomically derived disomic embryonic cells. "Thomson et al ...teach the specific art-recognized What Thompson did not teach, nor anticipate, is that trisomic cell lines can revert to "normal" disomic cell lines. In re Edwards, 568 F 2d at 1351, 196 U.S.P.Q.2d at 468 the Court held that the detailed disclosure of the process and possible reactants were sufficient to provide a "written description" of one of the possible products of that reaction. And, In re Ruschig 54 CCPA 1551, 154 USPQ 118 (CCPA 1967) that a sufficient disclosure is "one that marks a trial through the woods by supplying blaze marks on the trees". We believe we have marked a clear trail to making stem cells from trisomically derived disomic embryonic cell lines.

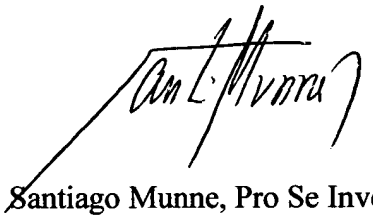
In addition, I can testify that I have assigned colleagues who are skilled in the art in making stem cells from these cell lines with only the specification and references detailed in this patent application and they have successfully isolated stem cells (RG44, RG56, RG92, RG93, RG94, RGK230) that have the characteristic epitopes of stem cells (SSEA-1, SSEA-3, SSEA-4, TRA 1-60, TRA 1-81, OCT 4, Lakaline phosphatase).

Examiner acknowledges that the specification provides guidance to show that embryonic cells can be produced, examiner fails to acknowledge that the inherent characteristic of embryonic cells is that by definition embryonic cells have differentiation potential of pluripotent cells. Pluripontent differentiation is an intrinsic *a posteriori* function for an *a priori* defined embryonic cell.
Examiner herself almost alludes to this in her anticipation argument of Claims 1 and 2 claiming that disomic cells are the equivalent to the disomic cell lines of Thompson's definition of stem cells.

Claim Rejection of 35 USC102
Examiner rejects Claims 1 and 2 as being anticipated by Thompson because the product and not the process in this case disomic cell lines appear to be identical. However, this is a very naïve interpretation of a complex structure such as cell lines.
All the previous rulings, which Examiner cites, have addressed similarity of product that were chemically synthesizable.
"Written Description Requirement" we would at this point introduce the most recent ruling of the Supreme Court in *Festo Corp v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.* Decided May 28th, 2002. In contrast to the previous holdings such as in certain chemical and pharmaceutical cases, an adequate written description of DNA, including cDNA incorporated into recombinant plasmids and microorganisms, "requires a precise definition, such as by structure, formula, chemical name or physical properties." **But the case is quite specific in that this criteria exists only when the process of making the product is unknown**. In *Fiers v Revel* 984 F 2d 1164, 1169, 25 USPQ2d 1601, 1505 (Fed.Cir.1993)
"Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties". *Fiers* requires the process to define the product.
In *re Bell*, 991 F.2d 781, 785, 26 USPQ 1529, 1532 (Fed Cir. 1993) " A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein..."
Here we have two identical end product protein sequences, yet each are coded by different messenger RNA. The process of making the protein is different. And, the cell lines making the identical protein with different codings are separately and distinctly patentable.
Similarly, the Thomson disomic cell line and stem cells derived therefrom is made by a different process than the trisomically derived disomic cell line and stem cells therefrom and these disomic cell lines and the derived stem cells are separately and distinctly patentable.
In addition, we believe that our trisomically derived disomic cell lines have structural and karyotypic characteristics different from Thomson non trisomically derived disomic cell lines. It is statistically unlikely that such a complex structure as a cell isolated for different selected criteria would converge into identical cell types.
What is clear is that neither Thompson nor Shamblatt anticipated trisomically derived disomic cell lines and stem cells derived therein. There is no mention of trisomy in any references presented by Examiner and anticipation requires all the elements of the claim a priori and not just a mix of elements and a hind sight combination *a posteriori* (Hybridtech v Monoclonal Antibody inc 231U.S.P.Q.81 (federal circuit 1986)).

Therefore, we submit that Claims 1, 2, 3, 4 are properly described, the inventor having complete possession of the invention, that the specification and claims allow any practitioner in the art to make trisomically derived disomic cells and stem cells therefrom and that neither Thomson nor Shamblott, separately, nor put together anticipate all elements of the claim, nor even the concept of trisomically derived disomic cell lines. We plead that examiner accept the claims. In addition, we suggest that examiner under Rule MPEP 707.07(j)S, if the Examiner finds patentable subject mater disclosed, but feels that Inventor's present claims are not entirely suitable, the Examiner draft one or more allowable claims for the applicant.

Sincerely yours,



Santiago Munne, Pro Se Inventor